

K041826

9.0 510(k) Summary

APR 27 2005

Applicant Name: EKOS Corporation

Address: 22030 20th Ave. SE, Suite 101
Bothell, WA 98021

Contact Person: Jocelyn Kersten
Director, Regulatory Affairs

Telephone: (425) 482-1108 X 287

Fax: (425) 482-1109

Device: EKOS Micro-Infusion System

Classification: CFR 870.1210 – Continuous Flush Catheter

Panel: Cardiovascular

Product Code: KRA

Intended Use: The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro-Infusion System may be used for controlled, regional infusion into selected vessels and is not intended for use in the coronary vasculature.

Device Description: The EKOS Micro-Infusion System is an infusion catheter system designed to deliver ultrasound energy through a transducer element at the distal catheter tip. This device is intended to deliver angiographic contrast material into the neurovasculature.

Predicate Basis: The EKOS Micro-Infusion System is substantially equivalent to other legally marketed devices. These devices include

- EKOS Peripheral Infusion System (K030637)
- Boston Scientific Corporation: Magic Infusion Catheter (K923368 & K023351)
- Boston Scientific Corporation: Renegade Hi-Flo Microcatheter (K000177)
- Boston Scientific Corporation Turbo-Tracker Microcatheter (K960806)
- BioSphere Medical EmboCath Hydrophilic Infusion Catheter (K003105)
- Spencer Technologies TCD 100M Transcranial Doppler

(K002533)

Performance:

EKOS has conducted preclinical bench and animal studies with the EKOS Micro-Infusion System. These studies demonstrate that the performance of the EKOS Micro-Infusion System meets its design specifications and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jocelyn Kersten
Director, Regulatory Affairs
EKOS Corporation
22030 20th Avenue SE, Suite 101
Bothell, Washington 98021

APR 27 2005

Re: K041826
Trade Name: EKOS Micro-Infusion System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: NUI
Dated: March 2, 2005
Received: March 3, 2005

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear as a box warning, immediately following the indications for use, in the device's labeling:

"The safety and effectiveness of the EKOS Micro-Infusion System for thrombolytic therapy in the neurovasculature have not been established. Further clinical studies are necessary to ensure that use of devices to deliver thrombolytic therapy into the neurovasculature does not result in an increased incidence of adverse events (e.g., intracranial hemorrhage)."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041826

Device Name: EKOS Micro-Infusion System

Indications For Use:

The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro-Infusion System may be used for controlled, regional infusion into selected vessels and is not intended for use in the coronary vasculature.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A handwritten signature in black ink, appearing to read "V. G. K. T. H.", is written over the signature line.